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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/781,177	02/18/2004	Rafail Zubok	SPINE 3.0-455 CIP CONT I	1815
530 7590 01/30/2007 LERNER, DAVID, LITTENBERG, KRUMHOLZ & MENTLIK 600 SOUTH AVENUE WEST WESTFIELD, NJ 07090			EXAMINER WOODALL, NICHOLAS W	
			ART UNIT 3733	PAPER NUMBER
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		01/30/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/781,177

Applicant(s)

ZUBOK ET AL.

Examiner

Nicholas Woodall

Art Unit

3733

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 7-13, and 15-20 is/are rejected.
- 7) ☒ Claim(s) 6 and 14 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 05/06/2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>06/15/2004;01/28/2005</u> . | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

Specification

1. The disclosure is objected to because of the following informalities: Claim 13 states, "wherein a head square area of at least one of the trials differ form a head square area of at least one other of the trials." The examiner is unable find this language and a description of the meaning of this language in the specification. The examiner believes the applicant is describing that each device has a different head thickness and therefore has a different head square area because of this difference in thickness. However, the applicant states in claim 14 that two devices with substantially the same head thickness have different head square areas. The examiner is unable to find any support for this claim in the specification. The only dimension the applicant discusses changing with regards to the head portions of the devices is the thickness. Therefore, if the thickness is substantially the same and no other dimensions are disclosed to be different, then the examiner believes the square are would also be substantially the same. Regarding claim 13, the examiner is going to understand claim 13 to mean that the change in thickness between the different head portions of the device create the different square areas for the head portions for the devices for examination purposes. Appropriate correction is required.

Claim Objections

2. Claim 14 is objected to because of the following informalities: in line 5 the word at is misspelled. Appropriate correction is required.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 1-4 and 10-15 are rejected under 35 U.S.C. 102(e) as being anticipated by Foley (U.S. Patent 7,063,725 B2).

Regarding priority for claims 1-20, the examiner believes the claims are supported in application 10/688,632 filed on 10/17/2003, but the claims are not supported in application 10/382,702 filed on 03/06/2003. Therefore, for examination the claims will have a priority date of 10/17/2003. Regarding claim 1, Foley discloses a device comprising a shaft that includes a handle and a head disposed at a distal end of the shaft. The head includes a first surface and a second surface that are spaced apart by a distance (see Figure 1 below). Regarding claim 2, Foley discloses a device wherein the first surface has a generally oval footprint area and the second surface also includes an area. Regarding claim 3, Foley discloses a device wherein at least one of the first surface includes a substantially convex area or the second surface includes a substantially flat area. Regarding claim 4, Foley discloses a device wherein at least one of the first surface is tapered towards the distal end or the second surface is tapered towards the distal end. Regarding claim 10, Foley discloses a set of devices wherein

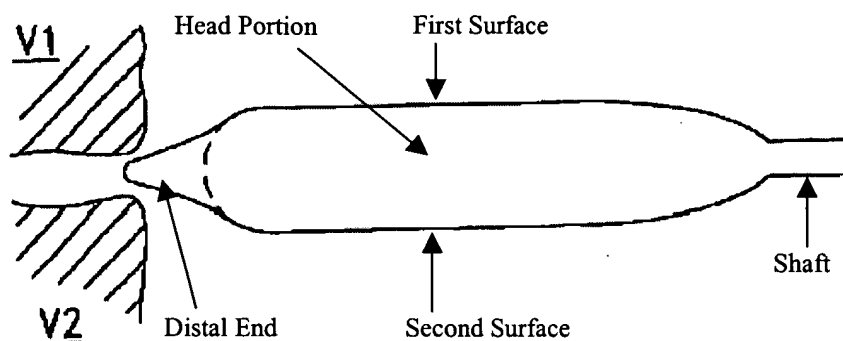
Art Unit: 3733

each device comprises a shaft having a handle at a proximal end and a head disposed at a distal end of the shaft. The head includes a first surface and a second surface that are spaced apart. Foley further discloses the set of devices have head portions that differ in size (column 18 lines 42-55). Regarding claims 11 and 12, Foley discloses a set of devices wherein the heads of the devices differ in thickness by about 1 mm (column 7 lines 3-7). Regarding claim, Foley discloses a set of devices wherein a square area of the head portions is different between the devices. Since Foley discloses a set of devices that have different thickness the devices also have a square area that is different. Regarding claim 15, Foley discloses a set of device further including one or more disc replacement devices (column 18 lines 42-55). Regarding claim 16, Foley discloses a method of using a device as discussed above comprising the steps of inserting a first trial into one of the intervertebral disc spaces to facilitate at least some distraction of the vertebral bones in a direction along a longitudinal axis and inserting a second trial into the intervertebral disc space to facilitate at least some further distraction of the vertebral bones along the longitudinal axis, where the second trial has a larger head thickness, measured substantially from the first surface to the second surface, than that of the first trial (column 19 lines 22-33). Regarding claims 17-20, Foley discloses a device that can be inherently used by a method as discussed above further including the steps of levering the handle of at least one of the first and second trials to facilitate the distraction of the vertebral bones (claim 17), repeating the insertion of further trials having a larger and larger head thickness to facilitate the distraction of the vertebral bones to a target distance (claim 18), wherein the target distance is one

Art Unit: 3733

that substantially maximizes the intervertebral space while substantially preserving an annulus and ligaments associated with the vertebral bones (claim 19), and inserting an intervertebral disc replacement device into the intervertebral space after it has been distracted to the target distance.

Figure 1



Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Foley (U.S. Patent 7,063,725 B2).

Regarding claim 5, Foley discloses a device wherein the head portion of the device includes a first surface and a second surface as discussed above. Foley discloses the first and second surfaces of the head portion can be tapered at an angle.

Art Unit: 3733

Foley fails to disclose the first surface of the head portion to be tapered at an angle of about 5 degrees and the second surface of the head portion to be tapered at an angle of about 4 degrees. It would have been obvious to one having ordinary skill in the art at the time the invention was made to manufacture the head portion of the device of Foley with a first surface tapered at an angle of about 5 degrees and the second surface tapered at an angle of about 4 degrees, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. In re Boesch, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

7. Claims 7-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Foley (U.S. Patent 7,063,725 B2) in view of Michelson (U.S. Publication 2003/0135279).

Regarding claim 7, Foley discloses the invention as claimed as discussed above except for the device further comprising a stop member. Michelson discloses a device wherein the device includes a shaft with a handle and a head portion further including a stop member (claim 7) that extends transversely at an anterior end of the head portion (claims 8 and 9) in order to prevent over penetration of the device (paragraph 88). It would have been obvious to one having ordinary skill in the art at the time the invention was made to manufacture the device of Foley to further include a stop member in view of Michelson in order to prevent over penetration of the device.

Allowable Subject Matter

8. Claim 6 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Art Unit: 3733

Conclusion

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. See PTO-892 for cited references the examiner felt were relevant to the application.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nicholas Woodall whose telephone number is 571-272-5204. The examiner can normally be reached on Monday to Friday 8:00 to 5:30 EST..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

NWW



EDUARDO C. ROBERT
SUPERVISORY PATENT EXAMINER